

REMARKS

This Response and Amendment is in response to the Office Action mailed on October 3, 2002. Reconsideration of this application is respectfully requested.

Allowable Subject Matter

Applicants acknowledge, with appreciation, the allowance of Claims 91-99 and 101-103 and the indicated allowability of Claims 16, 28-31, 48, 59-61, 73-76, 87-90 and 109-111, if rewritten in independent form to include all of the limitations of the base claim and any intervening claims and any applicable rejections under 35 U.S.C. § 112.

Summary of Claim Amendments

Claims 2, 3, 10, 26, 35, 36, 42, 56-58, 61, 71, 85, 100 and 108 have been cancelled without disclaimer or prejudice to presenting them in this or a later-filed application.

Independent claim 1 has been amended to substantially include the limitations of claims 2 and 3 and to specify a control device operable to control the movement of the syringe.

Independent claim 34 has been amended to substantially include the limitations of claims 35 and 36 and to specify a control device operable to control the rotation of the syringe.

Independent claim 49 has been amended to substantially include the limitations of allowable claim 61.

Dependent claims 8, 9 and 41 have been amended to make the language thereof consistent with independent claims 1 and 34, respectively.

Dependent claims 16 and 31 have been amended to correct the dependency thereof.

New dependent claims 112-143 have been added to further define the claimed inventions.

Because the amended and new claims are fully supported by the original specification (e.g., pgs. 2, 3, 6 and 8-10) and drawings (e.g., Figures 1 and 2), Applicants submit that no new matter has been added.

Specification Objection

The Office Action objected to the specification as failing to provide proper antecedent basis for the following claim terms: “movement mechanism,” “means for mounting a syringe” and “means cooperable.” This objection is respectfully traversed.

Applicant submits that the noted claim terms were presented in the original claims and, therefore, constitute part of the specification as filed. The noted terms may be represented by a number of structural components in the specification. As an illustrative example, the “movement mechanism” may be an “accessory” (page 6), a “rocker motor 11” (page 8), a “lifting motor 19”, a “linkage 20”, a pivot joint 18”, a “vibratory agitator” and a “connecting rod 21”. Further, the (1) “means for mounting a syringe” on the injector and (2) “means cooperable” with the injector means for mounting the syringe on the injector are shown in Figures 1 and 2 as recesses defined in the injector and corresponding flanges or detents on the rear end of the syringe 1.

Claims Objection

The Office Action objected to Claims 16 and 31 under 37 C.F.R. § 1.75© as being in improper multiple dependent form. To overcome the objection, Applicant has amended Claims 16 and 31 to make each of them depend from a single claim.

Section 112 Rejection

The Office Action rejected Claims 10, 26, 42, 58, 71, 85, 100 and 108 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

As noted above, Applicant has cancelled Claims 10, 26, 42, 58, 71, 85, 100 and 108 without disclaimer or prejudice to presenting them in this or a later-filed application. Therefore, Applicant submits that the Section 112 rejection is moot.

Prior Art Rejections

1. The Office Action rejected claims 1-10, 13-15, 34-42, 45-47 and 49-58 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 3,789,670 to Rosenwald (“the Rosenwald patent”). This rejection is respectfully traversed.

As provided above, Applicants have amended independent claims 1 and 34 to require, *inter alia*, (1) an ultrasound contrast agent and (2) a control device operable to control the movement / rotation of the syringe induced by the movement mechanism to substantially maintain the homogeneity and integrity of the ultrasound contrast fluid without substantially impairing the diagnostic properties thereof. Also, as claimed,

Applicant submits that the movement mechanism is defined as being part of the injector system, and not as a user of the injector system.

Applicant submits that the Rosenwald patent does not disclose an ultrasound contrast agent disposed in a syringe or a control device operable to control the movement / rotation of a syringe to substantially maintain the homogeneity and integrity of the ultrasound contrast fluid without substantially impairing the diagnostic properties thereof.

As explained, for example, in the Summary of the Invention (pages 2-4) of the present application, ultrasound contrast agents are delicate fluids whose constituent parts dissociate over time. To maintain the diagnostic properties of the ultrasound contrast agents, the agents must be agitated to a sufficient degree to maintain the homogeneity thereof while not destroying (i.e., by shear forces) the particles.

The Detailed Description, in Examples 1 and 2, describes Doppler intensity curves obtained for a particular ultrasound contrast agent, Levovist™, at different concentrations and at varying levels of agitation. These “agitated” curves were plotted against Doppler intensity curves for “non-agitated” Levovist (see Figures 3-6).

Applicant submits that the Rosenwald patent is deficient in this respect, and does not disclose or suggest a control device operable to control the movement of a syringe to a degree wherein the homogeneity and integrity of the ultrasound contrast fluid is substantially maintained without substantially impairing its diagnostic properties.

For at least the above reasons, Applicants submit that the Rosenwald patent does not disclose each and every limitation of independent claims 1 and 34, and that the rejection based thereon should be withdrawn.

With respect to independent claim 49, Applicant submits that the rejection is now moot. As provided above, claim 49 has been amended to include the limitations of allowable claim 61.

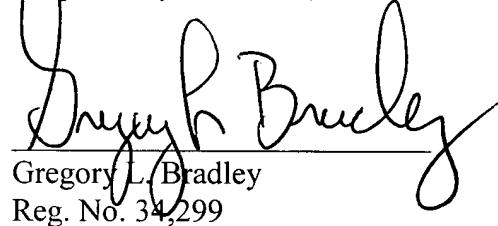
2. The Office Action rejected Claims 1-9, 11, 12, 17-25, 27, 32-41, 43, 44, 62-70, 72, 77-84, 86 and 104-107 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,383,858 to Reilly et al. in view of U.S. Patent No. 6,317,623 to Griffiths et al. (“the Griffiths patent”). This rejection is now moot.

Pursuant to 37 C.F.R. § 1.55(a)(4) and MPEP § 706.02(b), Applicant hereby perfects the foreign priority claim submitted in this application to German Application No. 198 40 532.4, filed on August 28, 1998. An English translation of the German priority application, as well as a statement of accuracy, is submitted herewith.

By perfecting the foreign priority claim, Applicant’s application will antedate the March 12, 1999, filing date of the Griffiths patent, and therefore remove it as prior art. Applicant submits that the Section 103 rejection based on the Griffiths patent is now moot in light of the perfected foreign priority claim.

In view of the foregoing amendments and remarks, Applicants submit that the application is now in condition for allowance. Reconsideration of this application is respectfully requested.

Respectfully submitted,



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CERTIFICATE OF MAILING

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on January 21, 2003, with sufficient postage as first-class mail in an envelope addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

Gregory L. Bradley



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VERSIONS WITH MARKINGS TO SHOW CHANGES MADE

1. (Amended) A syringe for use with an injector [having] system comprising a movement mechanism and a control device operably associated [therewith] with the movement mechanism, the syringe comprising:

a body comprising a distal discharge end;
a plunger movably disposed within the body; and
at least one agitation element disposed within the body between the plunger and the distal discharge end, the at least one agitation element operable to agitate [a] an ultrasound contrast fluid in the syringe when the syringe is moved [with respect to gravity] by means of the movement mechanism operably associated with the injector system,

the control device operable to control the movement of the syringe induced by the movement mechanism to substantially maintain the homogeneity and integrity of the ultrasound contrast fluid without substantially impairing the diagnostic properties thereof.

8. (Amended) The syringe of Claim 1 wherein the movement mechanism operably associated with the injector system is operable to move the syringe in one or more of circular, partially circular and linear motions.

9. (Amended) The syringe of Claim 1 wherein the movement mechanism operably associated with the injector system is operable to move the syringe in a rotational motion.

16. (Amended) The syringe of [Claims 13-15] Claim 13 wherein the recess comprises an annular recess.

31. (Amended) The injector system of [Claims 28-30] Claim 28 wherein the recess comprises an annular recess.

34. (Amended) A syringe for use with an injector [having] system comprising a movement mechanism and a control device operably associated [therewith] with the movement mechanism, the syringe comprising:

a body comprising a distal discharge end;
a plunger movably disposed within the body; and
at least one agitation element disposed within the body between the plunger and the distal discharge end, the at least one agitation element operable to agitate [a] an ultrasound contrast fluid in the syringe when the syringe is rotated [with respect to gravity] by means of the movement mechanism,

the control device operable to control the rotation of the syringe induced by the movement mechanism to substantially maintain the homogeneity and integrity of the ultrasound contrast fluid without substantially impairing the diagnostic properties thereof.

41. (Amended) The syringe of Claim 34 wherein the movement mechanism operably associated with the injector system is further operable to move the syringe in one or more of circular, partially circular and linear motions.

49. (Amended) A syringe [for use with an injector having a movement mechanism operably associated therewith, the syringe] comprising:

- a body comprising a distal discharge end;
- a plunger movably disposed within the body;
- at least one agitation element disposed within the body between the plunger and the distal discharge end, the at least one agitation element operable to agitate a fluid in the syringe [when the syringe is moved with respect to gravity by means of the movement mechanism]; and

[a] an annular recess defined in the body of the syringe, the annular recess operable to accommodate the at least one agitation element.